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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/410,484	09/30/1999	JAN WADSTEIN	NATNUT-03972	6938

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EXAMINER	
ARNOLD, ERNST V	
ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/410,484	WADSTEIN ET AL.	
	Examiner	Art Unit	
	Ernst V. Arnold	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 8-18* is/are pending in the application.

4a) Of the above claim(s) *8 and 10-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 7 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 4-6 have been cancelled. Claims 8 and 10-18 have been withdrawn. Claims 1-3, 7 and 9 are under examination.

The Declaration by Dr. Inge Bruheim is duly noted and discussed below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 7 and 9 remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al. (US 5,554,646) in view of Kawamura et al. (Hypertension 1996, 27, 408-413) and Shinitzky et al. (US 4,474,773).

Applicant claims a method of treating hypertension in humans.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Cook et al. disclose a method of reducing body fat comprising the administration of a safe and effective amount of conjugated linoleic acid (Abstract and claims 1-9). Cook et al. define conjugated linoleic acid as including mixtures and salts thereof (Column 4, lines 21-26). Cook et al. disclose 9,11-octadecadienoic acid and 10,12-octadecadienoic acid as conjugated linoleic acids obtained by their methods and therefore reading on instant claim 3 (Column 4, lines 37-41 and 60-67). Other geometric isomers, including cis-9, cis-11, can be obtained consequently reading on instant claim 2 (Column 4, lines 48-59 and column 5, lines 3-8)). Cook et al. disclose the addition of 0.1 to 10 grams of conjugated linoleic acid to the diet of humans as a food supplement thus reading on instant claim 9 (Column 2, example 3). Since the material was ingested, then the conjugated linoleic acid was administered orally and therefore reads on instant claim 7.

Kawamura et al. provide a nexus teaching between hypertension, weight loss and decreases in blood pressure. Kawamura et al. teach that changes in body weight exhibited significant correlations with blood pressure reduction in hypertensive overweight human patients (Abstract, pages 1 and 2; page 9, final paragraph).

Shinitzky et al. teach methods of treating warmblooded mammals comprising administering a pharmaceutically effective amount of a composition comprising 5-10% linoleic acid for the treatment of hypertension (Claims 1, 4 and 24).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Cooke et al. do not expressly teach a method of treating hypertension in humans.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to treat a hypertensive human patient with the conjugated linoleic acid method of Cooke et al. and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Cooke et al. provide a method of reducing body fat and Kawamura et al. teach that reduction in weight in hypertensive patients results in a lowering of blood pressure. Furthermore, Shinitzky et al. provide the teaching that linoleic acid (C18:2, cis-9, cis12) can be used to treat hypertension. Since conjugated linoleic acid is a mixture of positional and geometrical isomers of linoleic acid, then one of ordinary skill in the art would immediately envision conjugated linoleic acid in the treatment of hypertension. In fact, similar properties may normally be presumed when compounds are very close in structure. Dillon, 919 F.2d at 693, 696, 16 USPQ2d at 1901, 1904. See also In re Grabiak, 769 F.2d 729, 731, 226 USPQ 870, 871 (Fed. Cir. 1985) ("When chemical compounds have very close' structural similarities and similar utilities, without more a prima facie case may be made."). Thus, evidence of similar properties or evidence of any useful properties disclosed in the prior art that would be expected to be shared by the claimed invention weighs in favor of a conclusion that the claimed invention would

have been obvious. Dillon, 919 F.2d at 697-98, 16 USPQ2d at 1905; In re Wilder, 563 F.2d 457, 461, 195 USPQ 426, 430 (CCPA 1977); In re Linter, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972). Thus, the method of Cooke et al. is beneficial to the instantly claimed patient population and would have been obvious to one of ordinary skill in the art.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to arguments:

Applicant asserts that the Examiner has misstated the scope and content of the prior art. Applicant asserts that the Examiner's characterization of the secondary reference of Shinitzky is incorrect. The Examiner cannot agree. The Examiner has correctly stated that Shinitsky clearly claims a method of treating hypertension by administering a composition comprising from 5-10% linoleic acid (Claims 1, 4 and 24). Claim 24 recites the method and claim 4 recites linoleic acid. These claims are reproduced below for Applicant's benefit.

24. A method for treatment of warmblooded mammals, comprising administering a pharmaceutically effective quantity of a fraction of lipids from natural sources (AL) as recited in claims 1, 4, 2 or 8 for the treatment of the following conditions:
a. dysfunctions of the immune system;
b. increased vulnerability to bacterial contaminations;
c. hypertension; and
d. symptoms of withdrawal from morphine and alcohol.

4. A composition according to claim 3 where the fatty acid composition of the lipids is the following: Palmitic acid 35–45%, oleic acid 35–45%, linoleic acid 5–10%, stearic acid 5–7%, palmitoleic acid 2–3%, arachidonic acid 0.2–1%.

Applicant asserts that it could be any of the other components that is causing the reduction in hypertension and not linoleic acid. However, it is the Examiner's position that each component is treating hypertension because that is what the claim language clearly states. There can be no other interpretation of the claim.

Dr. Inge Bruheim correctly points out that the secondary reference of Shinitsky teaches treatment of hypertension by administering a complex mixture comprising linoleic acid. This is the correct claim interpretation. Dr. Bruheim states that Shinitsky et al. does not teach that linoleic acid can be used to treat hypertension or that among all the components of the complex mixture, linoleic acid is sufficient to treat hypertension. As stated above, Shinitsky et al. clearly recite a method that utilizes linoleic acid to treat

hypertension. The Examiner cannot make that statement any more clearly. Shinitsky et al. do not have to recite a method that utilizes solely linoleic acid. The Examiner also notes for the record the open claim language of the instant application.

Applicants next line of arguments is that the positional and geometric isomers of linoleic acid have different biological properties from standard linoleic acid and direct the Examiner to a list of publications that is alleged to support this line of reasoning. This line of argument is not persuasive because Cooke et al. teach that free linoleic acid is converted to conjugated linoleic acid in the animal (column 3, lines 52-60) reproduced below for Applicant's benefit.

> In another embodiment of the invention, free linoleic acid is administered to an animal which can convert the linoleic acid into CLA or which modulates the level of CLA in the body of an animal or a human. The linoleic acid is converted to CLA in the animal, probably by microorganisms in the animal's gastrointestinal system (S. F. Chin, J. M. Storkson, W. Liu, K. Albright, and M. W. Pariza, 1994, J. Nutr. 124: 694–701.

Therefore, any linoleic acid administered to an animal would be expected to be converted into conjugated linoleic acid and have all the benefits of action of conjugated linoleic acid as per the teachings of Cook et al.

With respect to the Saebo Declaration, Applicant attempted to establish that the action of conjugated linoleic acid in the body is complex and unpredictable. Applicant has misstated the scope of the art because Cook et al. teach predictable reduction in body fat. Cook et al. clearly teach predictable reduction in body fat, which is weight loss, and the art teaches the correlation between weight loss and reduction in blood pressure

in hypertension as explained above. It remains the Examiner's position that the method of Cook et al. will result in a reduction of body fat, hence a lowering of body weight, and a reduction in blood pressure in a hypertensive patient.

Applicants arguments are not persuasive and the rejection is maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ernst Arnold
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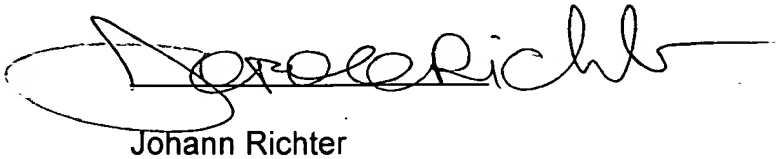
Art Unit 1616
May 02, 2006



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